

BREAST STAGING FORM

| CLINICAL Extent of disease before any treatment | STAGE CATEGORY DEFINITIONS | PATHOLOGIC Extent of disease through completion of definitive surgery |
|--|---|--|
| <input type="checkbox"/> y clinical – staging completed after neoadjuvant therapy but before subsequent surgery | TUMOR SIZE: _____ LATERALITY: <input type="checkbox"/> left <input type="checkbox"/> right <input type="checkbox"/> bilateral | <input type="checkbox"/> y pathologic – staging completed after neoadjuvant therapy AND subsequent surgery |
| <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> Tis <input type="checkbox"/> Tis (DCIS) <input type="checkbox"/> Tis (LCIS) <input type="checkbox"/> Tis (Paget's) | <p style="text-align: center;">PRIMARY TUMOR (T)</p> <p>Primary tumor cannot be assessed No evidence of primary tumor Carcinoma <i>in situ</i> Ductal carcinoma <i>in situ</i> Lobular carcinoma <i>in situ</i> Paget's disease of the nipple is NOT associated with invasive carcinoma and/or carcinoma <i>in situ</i> (DCIS and/or LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget's disease are categorized based on the size and characteristics of the parenchymal disease, although the presence of Paget's disease should still be noted</p> <p><input type="checkbox"/> T1 <input type="checkbox"/> T1mi <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T1c <input type="checkbox"/> T2 <input type="checkbox"/> T3 <input type="checkbox"/> T4 <input type="checkbox"/> T4a <input type="checkbox"/> T4b <input type="checkbox"/> T4b <input type="checkbox"/> T4c <input type="checkbox"/> T4c <input type="checkbox"/> T4d</p> <p>*Note: Invasion of the dermis alone does not qualify as T4. **Note: Inflammatory carcinoma is restricted to cases with typical skin changes involving a third or more of the skin of the breast. While the histologic presence of invasive carcinoma invading dermal lymphatics is supportive of the diagnosis, it is not required, nor is dermal lymphatic invasion without typical clinical findings sufficient for a diagnosis of inflammatory breast cancer.</p> | <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> Tis <input type="checkbox"/> Tis (DCIS) <input type="checkbox"/> Tis (LCIS) <input type="checkbox"/> Tis (Paget's) |
| <input type="checkbox"/> NX <input type="checkbox"/> pNX | <p style="text-align: center;">REGIONAL LYMPH NODES (N)</p> <p>Regional lymph nodes cannot be assessed (e.g., previously removed) Regional lymph nodes cannot be assessed (e.g., previously removed, or not removed for pathologic study)</p> <p><input type="checkbox"/> N0 <input type="checkbox"/> pN0 <input type="checkbox"/> pN0(i-) <input type="checkbox"/> pN0(i+)</p> <p><input type="checkbox"/> pN0(mol-) <input type="checkbox"/> pN0(mol+)</p> <p>No regional lymph node metastases No regional lymph node metastasis identified histologically No regional lymph node metastases histologically, negative IHC Malignant cells in regional lymph node(s) no greater than 0.2 mm (detected by H&E or IHC including ITC) No regional lymph node metastases histologically, negative molecular findings (RT-PCR) Positive molecular findings (RT-PCR), but no regional lymph node metastases detected by histology or IHC</p> | <input type="checkbox"/> NX <input type="checkbox"/> pNX* |
| HOSPITAL NAME/ADDRESS | PATIENT NAME/INFORMATION | |

(continued on next page)

BREAST STAGING FORM

| | |
|---|---|
| <input type="checkbox"/> N1 pN1 Metastases to movable ipsilateral level I, II axillary lymph node(s) Micrometastases; or metastases in 1 to 3 axillary lymph nodes; and/or in internal mammary nodes with metastases detected by sentinel lymph node biopsy but not clinically detected** pN1mi Micrometastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm) pN1a Metastases in 1 to 3 axillary lymph nodes, at least one metastasis greater than 2.0 mm pN1b Metastases in internal mammary nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected** pN1c Metastases in 1 to 3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected** <input type="checkbox"/> N2 Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in the <i>absence</i> of clinically evident axillary lymph node metastases pN2 Metastases in 4 to 9 axillary lymph nodes; or in clinically detected*** internal mammary lymph nodes in the <i>absence</i> of axillary lymph node metastases <input type="checkbox"/> N2a Metastases in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures pN2a Metastases in 4 to 9 axillary lymph nodes (at least one tumor deposit greater than 2.0 mm) <input type="checkbox"/> N2b Metastases only in clinically detected*** ipsilateral internal mammary nodes and in the <i>absence</i> of clinically evident axillary lymph node metastases pN2b Metastases in clinically detected*** internal mammary lymph nodes in the <i>absence</i> of axillary lymph node metastases <input type="checkbox"/> N3 Metastases in ipsilateral infracavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement; or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement pN3 Metastases in 10 or more axillary lymph nodes; or in infracavicular (level III axillary) lymph nodes; or in clinically detected*** ipsilateral internal mammary lymph nodes in the <i>presence</i> of 1 or more positive level I, II axillary lymph nodes; or in more than 3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected**; or in ipsilateral supraclavicular lymph nodes <input type="checkbox"/> N3a pN3a Metastases in ipsilateral infracavicular lymph node(s) Metastases in 10 or more axillary lymph nodes (at least one tumor deposit greater than 2.0 mm); or metastases to the infracavicular (level III axillary lymph) nodes <input type="checkbox"/> N3b Metastases in ipsilateral internal mammary lymph node(s) and axillary lymph node(s) pN3b Metastases in clinically detected*** ipsilateral internal mammary lymph nodes in the <i>presence</i> of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected** <input type="checkbox"/> N3c Metastases in ipsilateral supraclavicular lymph node(s) | N1 <input type="checkbox"/> pN1 <input type="checkbox"/> pN1mi <input type="checkbox"/> pN1a <input type="checkbox"/> pN1b <input type="checkbox"/> pN1c <input type="checkbox"/> pN2 <input type="checkbox"/> pN2a <input type="checkbox"/> pN2b <input type="checkbox"/> pN3 <input type="checkbox"/> pN3a <input type="checkbox"/> pN3b |
|---|---|

HOSPITAL NAME/ADDRESS

PATIENT NAME/INFORMATION

(continued from previous page)

BREAST STAGING FORM

| | |
|---|---|
| <p>pN3c</p> <p>Metastases in ipsilateral supraclavicular lymph nodes</p> <p>*Classification is based on axillary lymph node dissection with or without sentinel lymph node biopsy. Classification based solely on sentinel lymph node biopsy without subsequent axillary lymph node dissection is designated (sn) for "sentinel node," for example, pN0(sn).</p> <p>**Note: <i>Not clinically detected</i> is defined as not detected by imaging studies (excluding lymphoscintigraphy) or not detected by clinical examination.</p> <p>***Note: <i>Clinically detected</i> is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination and having characteristics highly suspicious for malignancy or a presumed pathologic macrometastasis based on fine needle aspiration biopsy with cytologic examination. Confirmation of clinically detected metastatic disease by fine needle aspiration without excision biopsy is designated with an (f) suffix, for example, cN3a(f). Excisional biopsy of a lymph node or biopsy of a sentinel node, in the absence of assignment of a pT, is classified as a clinical N, for example, cN1. Information regarding the confirmation of the nodal status will be designated in sitespecific factors as clinical, fine needle aspiration, core biopsy, or sentinel lymph node biopsy. Pathologic classification (pN) is used for excision or sentinel lymph node biopsy only in conjunction with a pathologic T assignment.</p> <p><i>Note:</i> Isolated tumor cell clusters (ITC) are defined as small clusters of cells not greater than 0.2 mm, or single tumor cells, or a cluster of fewer than 200 cells in a single histologic cross-section. ITCs may be detected by routine histology or by immunohistochemical (IHC) methods. Nodes containing only ITCs are excluded from the total positive node count for purposes of N classification but should be included in the total number of nodes evaluated</p> | <p><input type="checkbox"/> pN3c</p> |
| <p><input type="checkbox"/> M0</p> <p>No clinical or radiographic evidence of distant metastases (no pathologic M0; use clinical M to complete stage group)</p> <p><input type="checkbox"/> cM0(i+)</p> <p>No clinical or radiographic evidence of distant metastases, but deposits of molecularly or microscopically detected tumor cells in circulating blood, bone marrow or other non-regional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastases</p> <p><input type="checkbox"/> M1</p> <p>Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2 mm</p> | <p><input type="checkbox"/> M1</p> |

| | |
|------------------------------|---------------------------------|
| HOSPITAL NAME/ADDRESS | PATIENT NAME/INFORMATION |
|------------------------------|---------------------------------|

(continued on next page)

BREAST STAGING FORM

ANATOMIC STAGE • PROGNOSTIC GROUPS

| CLINICAL | | | | PATHOLOGIC | | | |
|-------------------------------------|-------|-------|----|-------------------------------------|-------|-------|----|
| GROUP | T | N | M | GROUP | T | N | M |
| <input type="checkbox"/> 0 | Tis | N0 | M0 | <input type="checkbox"/> 0 | Tis | N0 | M0 |
| <input type="checkbox"/> IA | T1* | N0 | M0 | <input type="checkbox"/> IA | T1* | N0 | M0 |
| <input type="checkbox"/> IB | T0 | N1mi | M0 | <input type="checkbox"/> IB | T0 | N1mi | M0 |
| | T1* | N1mi | M0 | | T1* | N1mi | M0 |
| <input type="checkbox"/> IIA | T0 | N1** | M0 | <input type="checkbox"/> IIA | T0 | N1** | M0 |
| | T1* | N1** | M0 | | T1* | N1** | M0 |
| | T2 | N0 | M0 | | T2 | N0 | M0 |
| <input type="checkbox"/> IIB | T2 | N1 | M0 | <input type="checkbox"/> IIB | T2 | N1 | M0 |
| | T3 | N0 | M0 | | T3 | N0 | M0 |
| <input type="checkbox"/> IIIA | T0 | N2 | M0 | <input type="checkbox"/> IIIA | T0 | N2 | M0 |
| | T1* | N2 | M0 | | T1* | N2 | M0 |
| | T2 | N2 | M0 | | T2 | N2 | M0 |
| | T3 | N1 | M0 | | T3 | N1 | M0 |
| | T3 | N2 | M0 | | T3 | N2 | M0 |
| <input type="checkbox"/> IIIB | T4 | N0 | M0 | <input type="checkbox"/> IIIB | T4 | N0 | M0 |
| | T4 | N1 | M0 | | T4 | N1 | M0 |
| | T4 | N2 | M0 | | T4 | N2 | M0 |
| <input type="checkbox"/> Stage IIIC | Any T | N3 | M0 | <input type="checkbox"/> Stage IIIC | Any T | N3 | M0 |
| <input type="checkbox"/> Stage IV | Any T | Any N | M1 | <input type="checkbox"/> Stage IV | Any T | Any N | M1 |

* T1 includes T1mi

** T0 and T1 tumors with nodal micrometastases only are excluded from Stage IIA and are classified Stage IB.

Stage unknown

* T1 includes T1mi

** T0 and T1 tumors with nodal micrometastases only are excluded from Stage IIA and are classified Stage IB.

Stage unknown

PROGNOSTIC FACTORS (SITE-SPECIFIC FACTORS)

REQUIRED FOR STAGING: None

CLINICALLY SIGNIFICANT:

Page's disease: _____

Tumor grade (Scarff-Bloom-Richardson system): _____

Estrogen receptor and test method (IHC, RT-PCR, other): _____

Progesterone receptor and test method (IHC, RT-PCR, other): _____

HER2 status and test method (IHC, FISH, CISH, RT-PCR, other): _____

Method of lymph node assessment (e.g., clinical, fine needle aspiration; core biopsy; sentinel lymph node biopsy): _____

IHC of regional lymph nodes: _____

Molecular studies of regional lymph nodes: _____

Distant metastases method of detection (clinical, radiographic, biopsy): _____

Circulating Tumor Cells (CTC) and method of detection (RT-PCR, immunomagnetic separation, other): _____

Disseminated Tumor Cells (DTC; bone marrow micrometastases) and method of detection (RT-PCR, immunohistochemical, other): _____

Multi-gene signature score: _____

Response to neoadjuvant therapy will be collected in the registry but does not affect the post-neoadjuvant stage: _____

General Notes:

For identification of special cases of TNM or pTNM classifications, the "m" suffix and "y," "r," and "a" prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis.

m suffix indicates the presence of multiple primary tumors in a single site and is recorded in parentheses: pT(m)NM.

y prefix indicates those cases in which classification is performed during or following initial multimodality therapy. The cTNM or pTNM category is identified by a "y" prefix. The ycTNM or ypTNM categorizes the extent of tumor actually present at the time of that examination. The "y" categorization is not an estimate of tumor prior to multimodality therapy.

r prefix indicates a recurrent tumor when staged after a disease-free interval, and is identified by the "r" prefix: rTNM.

a prefix designates the stage determined at autopsy: aTNM.

HOSPITAL NAME/ADDRESS

PATIENT NAME/INFORMATION

(continued from previous page)

BREAST STAGING FORM

Histologic Grade (G) (also known as overall grade)

Grading system

- 2 grade system
- 3 grade system
- 4 grade system
- No 2, 3, or 4 grade system is available

Grade

- Grade I or 1
- Grade II or 2
- Grade III or 3
- Grade IV or 4

General Notes (continued):

surgical margins is data field recorded by registrars describing the surgical margins of the resected primary site specimen as determined only by the pathology report.

neoadjuvant treatment is radiation therapy or systemic therapy (consisting of chemotherapy, hormone therapy, or immunotherapy) administered prior to a definitive surgical procedure. If the surgical procedure is not performed, the administered therapy no longer meets the definition of neoadjuvant therapy.

ADDITIONAL DESCRIPTORS

Lymphatic Vessel Invasion (L) and Venous Invasion (V) have been combined into Lymph-Vascular Invasion (LVI) for collection by cancer registrars. The College of American Pathologist (CAP) Checklist should be used as the primary source. Other sources may be used in the absence of a Checklist. Priority is given to positive results.

- Lymph-Vascular Invasion Not Present (absent)/Not Identified
- Lymph-Vascular Invasion Present/Identified
- Not Applicable
- Unknown/Indeterminate

Residual Tumor (R)

The absence or presence of residual tumor after treatment. In some cases treated with surgery and/or with neoadjuvant therapy there will be residual tumor at the primary site after treatment because of incomplete resection or local and regional disease that extends beyond the limit of ability of resection.

- RX Presence of residual tumor cannot be assessed
- R0 No residual tumor
- R1 Microscopic residual tumor
- R2 Macroscopic residual tumor

- Clinical stage was used in treatment planning (describe): _____
- National guidelines were used in treatment planning NCCN Other (describe): _____
-

Physician signature

Date/Time

HOSPITAL NAME/ADDRESS

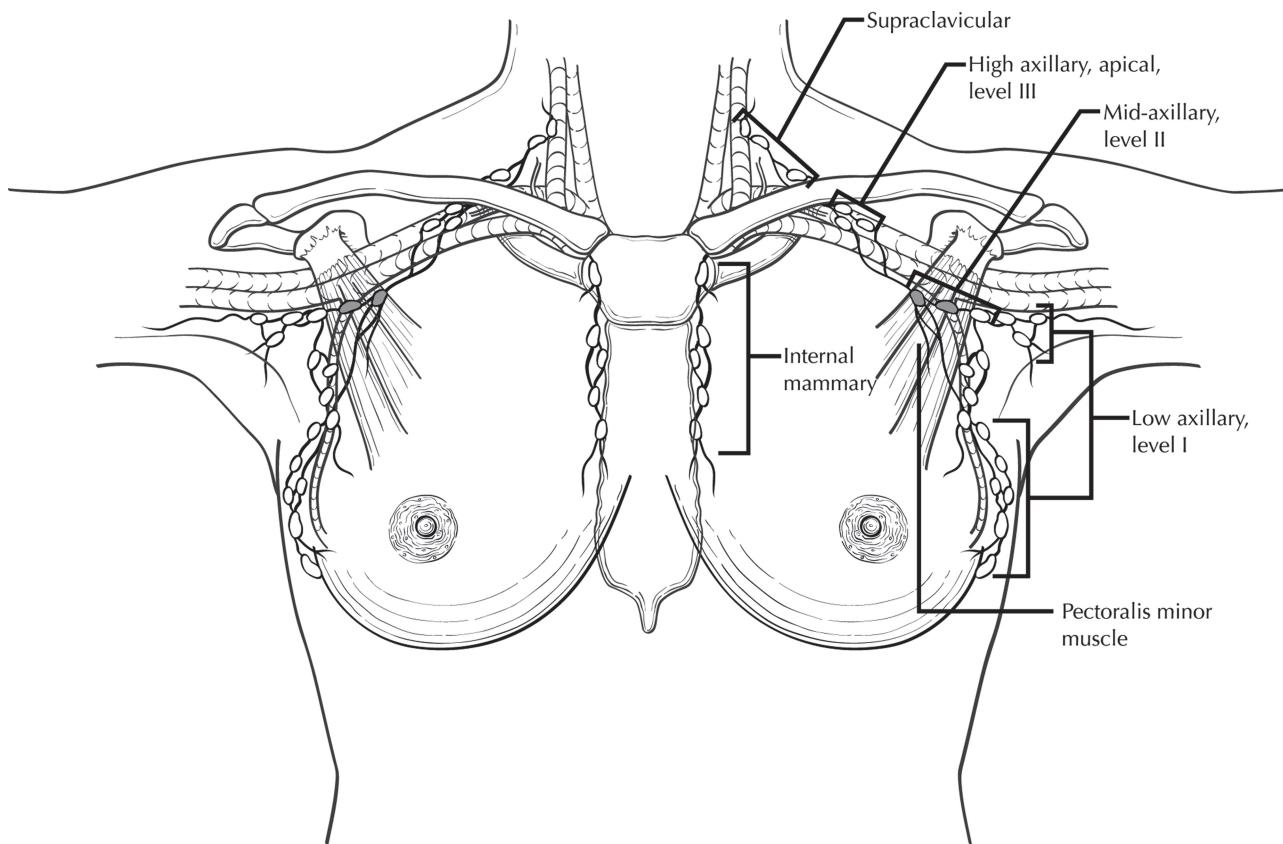
PATIENT NAME/INFORMATION

(continued on next page)

BREAST STAGING FORM

Illustration

Indicate on diagram primary tumor and regional nodes involved.



HOSPITAL NAME/ADDRESS

PATIENT NAME/INFORMATION

(continued from previous page)